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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/430,590	10/29/99	POULTER	R 674521-2001.

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HM12/0615

EXAMINER	
LEFFERS JR,G	
ART UNIT	**PAPER NUMBER**
1636	21

DATE MAILED: 06/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/430,590	POULTER ET AL.	
	Examiner	Art Unit	
	Gerald Leffers	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

ZETA ADAMS
PATENT ANALYST

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s): _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-6, 9-14, 17-21, drawn towards an unusual retrotransposon (pCal), transposable elements and fragments derived therefrom, expression vectors, DNA transfer system and retroviral-like carrier system, classified in class 536, subclass 23.1.

Groups 2-79. Claims 1-6 and 23, each group drawn to one of a series of putative retrotransposon sequences described in Figures 17-48 and 71 (SEQ ID NOS: 6-37 and 99-144), classified in class 536, subclass 23.1.

Group 80. Claims 7-8, drawn to methods of introducing DNA into the genome of a cell, classified in class 435, subclasses 455, 471.

Group 81. Claims 15-16 and 25-26, drawn to methods of gene disruption or altered expression/gene mapping comprising integrating a retrotransposon into the host cell genome, classified in class 435, subclass 6.

Group 82. Claim 22, drawn to a promoter isolated from a retrotransposon, classified in class 536, subclass 24.1.

Group 83. Claim 24, drawn to a method of assigning function to unknown sequence, classified in class 435, subclasses 6, 69.1.

Group 84. Claims 27-31, drawn to methods of using immunological, immunogenic, vaccine or therapeutic compositions comprising an isolated retrotransposon, classified in class 514, subclass 44.

Group 85. Claim 32, drawn to a method of detecting Candida comprising detecting the presence in a sample of a retrotransposon, classified in class 435, subclass 34.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-79 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different retrotransposons of Groups 1-79 are not disclosed as usable together. Also, the different retrotransposons or transposable elements are characterized by a distinct nucleic acid sequence encoding an element and associated polypeptides having distinct chemical, structural and functional characteristics and means of operation. Therefore, each of the different groups is capable of supporting a separate patent.

Groups 1-79 and Groups 80-81, 83-85 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the retrotransposon (or fragments, elements and systems derived therefrom) of Groups 1-79 can be used in the methods of each of the different groups (Groups 80-81, 83-85).

Inventions of Groups 1-79 and 82 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together. The promoter isolated from a given retrotransposon is not disclosed as being usable in conjunction with any of the nucleic acids of Groups 1-79.

Inventions of Group 82 and Groups 80-81, 83-85 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as usable together. The promoter isolated from a retrotransposon is not disclosed as used in the methods of Groups 81, 83-85.

The inventions of Groups 80-81, 83-85 are biologically and functionally different and distinct from each other and thus one does not render the others obvious. The methods of Groups 80-81, 83-85 comprise steps which are not required for or present in the methods of the other groups: introduction of a transposable element comprising a gene encoding a desired polypeptide into a target host cell (Group 80), integrating a retrotransposon into the genome of a yeast or Candida host cell to disrupt a gene or alter gene expression (Group 81), correlating expression of

a heterologous gene from a retrotransposon in a host cells and any observed phenotype (Group 83), administration of an immunogenic and/or therapeutic composition to an animal (Group 84), and detecting the presence of a retrotransposon (Group 85). The end result of the different methods are different from one another: incorporation of a gene encoding a desired polypeptide into a target host cell genome (Group 80), gene disruption and gene mapping (Group 81), assignment of putative function to an expressed, heterologous gene (Group 83), induction of an immunological response in an animal (Group 84), and detection of Candida in a sample (Group 85). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or different nonpatent literature search requirements (e.g. each of the different retrotransposons or transposable elements of Groups 1-79 requires a distinct nucleic acid and/or amino acid search of commercial databases), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Dr. Rob Schwartzman, can be reached on (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application, or relating to attachments to this office action, should be directed to the Patent Analyst Zeta Adams, whose telephone number is (703) 305-3291.

GLJ

G. Leffers, Jr.

Patent Examiner

Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER

June 6, 2001